K041750

JUL 2 3 2004

SECTION F: 510(k) Summary

510(k) SUMMARY
This summary of safety and effectiveness information is submitted in compliance with 21CFR807.92.

1. **Application Date:**
   June 25, 2004

2. **Applicant Information:**
   Polymer Technology Systems, Inc.
   7736 Zionsville Road
   Indianapolis, IN 46268
   Contact Person: Margo Enright
   Phone Number: 317-870-5610
   FAX Number: 317-870-5608
   e-mail: menright@PTSpanels.com

3. **Trade Names:**
   PTS PANELS Chol+Glu Test Panel

4. **Description:**
   The Chol+Glu Test Panel is a dry phase test strip that is constructed from a plastic strip holder that holds chemically treated membranes. When whole blood is placed on the test strip, the membranes first separate and isolate the red blood cells, allowing the serum/plasma to flow to the reaction membrane and react to produce a color change. The Chol+Glu Test Panel is for *in vitro* diagnostic use with a CardioChek brand (BioScanner Plus) reflectance photometer.

5. **Classification Names:**
   Cholesterol test system
   Glucose test system
   Panel: Clinical Chemistry 75
   Product Codes: CHH, CGA

6. **Facility Address:**
   7736 Zionsville Road
   Indianapolis, IN 46268

7. **Device Classification:**
   Class I (Regulations: 21 CFR 862.1345 and 862.1175)

8. **Intended Use:**
   The Chol+Glu Test Panel is intended to measure cholesterol and glucose in whole blood on a CardioChek brand analyzer. The test strips are intended to be used by healthcare professionals to measure blood cholesterol and glucose. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia and of pancreatic islet cell carcinoma.

9. **Reason for 510(k):**
Device Modification

10. **Predicate Device Information**
The predicate devices for determination of substantial equivalence are:
Name: BioScanner (PTS PANELS) Cholesterol and Glucose Test Strips
Device Company: Polymer Technology Systems, Inc.
510(k) Numbers: K972669, K981493, K013068

Similarities and Differences between Chol+Glu Test Panel and the Predicate Devices:

Similarities Between Predicate and Modified Device

Item	Predicates	Modified Device
Intended Use	Intended to measure glucose and cholesterol in whole blood.	**Same**
Technology	Dry chemistry test strip for use with PTS reflectance photometer.	**Same**
Measuring Ranges	Cholesterol: 100-400 mg/dL Glucose: 20-600 mg/dL	
Product Storage	Store in cool dry place at room temperature of 68-86°F.	**Same**
Specimen	Whole blood from fingerstick or venous blood collected in EDTA or heparin tube.	**Same**
Chemistry Methods	Glucose oxidase method for glucose and enzymatic (cholesterol esterase / oxidase) trinder method for cholesterol.	**Same**
Calibration Curve	Resides on a read-only memory (EEPROM) chip packaged with the test strips.	**Same**

Differences Between Predicate and Modified Device

Item	Predicates	Modified Device
Number of analytes per test strip.	One test per strip. Separate cholesterol single test strip and separate glucose test strip.	**Modified device combines cholesterol and glucose into single test strip.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 2 3 2004

Ms. Margo Enright
Manager of Clinical Affairs
Polymer Technology Systems, Inc.
7736 Zionsville Road
Indianapolis, IN 46268

Re: k041750
Trade/Device Name: Chol+ Glu Test Panel
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, CGA, CHH
Dated: June 25, 2004
Received: June 29, 2004

Dear Ms. Enright:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

JUL 1 2 2004

Indications for Use

510(k) Number (if known): K041750

Device Name: Chol + Glu Test Panel

Indications For Use:

The Chol+Glu Test Panel is intended to measure cholesterol and glucose in whole blood on a BioScanner Plus (CardioChek brand) analyzer. The test strips are intended to be used by healthcare professionals and individuals at home to measure blood cholesterol and glucose. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia and of pancreatic islet cell carcinoma.

Prescription Use _X_____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use __X_____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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